Remarks / Arguments

As a result of this amendment, claims 1-8, 10, 11, 13, 18, 19, and 21 are pending in the application. Claims 9, 12, 14-17, and 20 have been cancelled. Claims 7, 18, and 21 have been withdrawn. Claims 1-6, 8, 10, 11, 13, and 19 have been amended. No new matter has been added.

The amendment to the specification is to correct "Table 2" in the last line of the paragraph to read "Table 4".

The examiner states in the official action that claim 6 is multiple processes in one claim. Claim 6 has now been amended to recite only the process labeled "A". Applicants reserve the right to claim the other processes in one or more divisional applications.

The examiner states that the applicants' heterocyclic expressions in claim 1 are rejected under §112, 2nd paragraph. The examiner has no authority to reject particular language in any claim. He may only reject claims.

The examiner states that the first line of claim 1 should read "A compound of the formula (I)". He also states that the terms "substituted", "derivatives" and "general" are not acceptable terms. The applicants respond that formula (I) is in fact a general formula covering pyrazole derivatives which are variously substituted. It is deemed that the terms "substituted", "derivative", and "general" are acceptable. Nevertheless, applicants have amended the first line of claim 1 as the examiner requires.

In response to the examiner's numerous comments throughout the official action to the effect that claim language variously reciting heterocycles is indefinite and unsupported, the applicants have deleted most recitations of heterocycles. The remaining such recitations have been narrowed substantially.

The 1,3-oxazolidin-2-on-3-yl group now recited in claims 1, 2, and 3 is supported by example 15.

In claim 1 in the language reciting the joinder of groups R^2 and R^3 to form a fused six-membered heterocycle, the heterocycle is now defined as having up to 2 nitrogen atoms as the

heteroatoms. Support for this is found in original claims 2 and 3 and the corresponding portions of the specification wherein it is recited that the groups R^2 and R^3 form a fused phenyl, pyridyl, pyrimidinyl, pyrazinyl or pyridazinyl ring (claim 2) or a phenyl, pyridyl or pyrimidinyl ring (claim 3). There are only a limited number of six-membered heterocycles which contain as the heteroatom(s) 1 or 2 nitrogens, and these should not pose an undue burden on the examiner to consider.

The references to heterocycles at page 95, lines 15 and 29 have been revised to state "aromatic". The heterocycles being referred to on those created by joining R^2 and R^3.

Regarding the chemical structures shown at the bottom of page 93 and the top of page 94 in the definitions of groups R^9 and R^{10}, which the examiner maintains have no antecedent basis or support, these groups have been deleted from all claims.

The examiner has rejected claim 1 under 35 USC §112, 2nd paragraph and 1st paragraph, again faulting the language regarding heterocycles. The heterocycles issue has been discussed above.

The examiner states on Page 5 of the official action that the written description is considered inadequate. Substantially all of his discussion on this point relates to heterocycles. Applicants maintain that with the present amendments which have deleted recitation of most heterocyles in the claims and severely limited the remaining ones, this written description issue has now been addressed.

The examiner states that the double patenting question will be re-visited "once we have allowable language in the claims". The applicants presume the examiner is referring to a potential double patenting issue which he has not yet raised, relative to co-pending application Serial number 09/744,830, which is also being handled by the same examiner.

The examiner states that Claim 2 is rejected for the reasons noted in the rejection of Claim 1. The applicants believe that their amendments to claims 1, 2 and 3 are consistent and address the examiner's concerns with respect to all of these claims.

The examiner states that it is not known what fused phenyl means on page 104, line 7. Applicants respond that the language referred to by the examiner relates to the definition of the combination of groups R^2 and R^3, given on page 103 at lines 14 and 15 as indicated by the line

numbering in the left hand margin, wherein it is stated that R^2 and R^3, together with the double bond, form a fused phenyl, pyridyl, pyrimidinyl, pyrazinyl or pyridazinyl ring.

The examiner states that claim 3 is rejected for the reasons claim 1 was rejected. The applicants response relating to the rejection of claim 2 is equally applicable here.

Line 1 of claim 4 has been amended substantially in accordance with the examiner's suggestion.

The examiner inquires what the optional substituents in R^1 of claim 4 are. Claim 4 is a dependent claim referring to claim 1. Claim 1 recites that at least one of the substituents R^1, X and Y represents a saturated or partially unsaturated C_3-C_8 cycloalkyl group, which may optionally be mono- or poly-substituted by any of a number of listed substituents. In claim 4, the groups X and Y are both amino and the group R^1 is defined as a cycloalkyl which may be optionally substituted. Accordingly, the optional substituents for this group R^1 are the substituents listed in claim 1 for this portion of the molecule.

Claim 5 is a dependent claim referring to claim 4, and is deemed to be proper.

The examiner states that one process needs to be elected from claim 6. Claim 6 has now been amended to delete processes B, C and D, leaving claim 6 to deal only with process A.

Applicants acknowledge the withdrawal of claim 7. They reserve the right to pursue the subject matter of this claim in one or more divisional applications.

The examiner states that claims 8, 10 and 11 are not statutory, on grounds that they are not written in proper method or composition form. These claims have now been amended to recite pharmaceutical compositions in the usual way. Regarding the examiner's comment that additional ingredient claims cannot be examined here as they would not be of the same scope as the final genus, the applicants respond that claims 10 and 11 should ultimately be allowable once the claim to compounds of general formula (I) of claim 1 are determined to be allowable. Once this is determined, it should not matter what any other additional ingredients may be.

On page 9 of the official action, the examiner requires the applicants to elect one use of the claimed compounds, and suggests that the use recited in claim 17 be so elected. In response, the applicants elect to proceed with prosecution of a claim to a method of treatment for hypertension. Claim 13 has now been amended to recite treating hypertension, and claims 14,

15, 16, and 17 are now cancelled. Applicants reserve the right to pursue the subject matter of these claims in one or more divisional applications.

The examiner states that newly presented claims 19 and 20 are grouped with claim 6. Claim 19 is maintained as it relates to process "A" of original claim 6. Claim 20 is now canceled as it relates to process "B" of original claim 6. Claim 20 will be re-introduced if and when a claim to process B is prosecuted in a divisional application.

The examiner states that claims 18 and 21 are withdrawn, and on page 9 of the official action gives as his reasons the fact that these are "addition ingredient claims" which could not be examined here as they have additional ingredients that would keep them from being the same scope as claim 1. Applicants acknowledge the withdrawal, but would maintain that once the compounds of claim 1 are found to be patentable, then a claim to a method of using such compounds in combination with any other materials should also necessarily be patentable.

The examiner states on page 10 of the official action that a "broad disclosure of utility as in the cited claims cannot be deemed in compliance with 35 USC §101, and 35 USC §112, 1st paragraph," and states that the applicants should limit the method claims to a "specific utility". Applicants have now amended the method claims to recite treatment of hypertension.

The applicants disclose the several possible uses for the claimed compounds, beginning on page 50 of the specification. On page 53 of the specification the applicants demonstrate that a representative compound of the invention (example 1) stimulates recombinant soluble guanylate cyclase in vitro, and also stimulates soluble guanylate cyclase in primary endothelial cells. On page 54 of the specification, the applicants present evidence that the exemplary compound is vasorelaxant in vitro (in rabbits). On page 55, the applicants demonstrate that the exemplary compound reduces blood pressure in rats. It is deemed that these in vitro and in vivo tests demonstrate that the claimed compounds are useful in treating hypertension. These test results should also support the utility of the claimed compounds in the other indications as well.

On page 11 of the official action, the examiner states that the "how to use" requirements of 35 USC §112 are not met by disclosing only a pharmacological activity of the claimed compounds, if one skilled in the art would not be able to use the compounds effectively without

undue experimentation. The applicants respond that they have adequately disclosed how to use the compounds, and no undue experimentation would be required to use them.

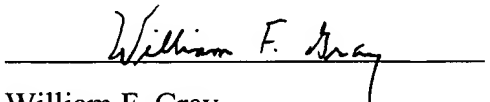
On page 11 of the official action, the examiner indicates that when the disclosed utility is a production of a physiological response, the dosage effective to achieve this response in a host must be disclosed. The applicants have done this in the specification at page 61.

On page 13 of the official action the examiner states that assay tests or laboratory screen tests are not acceptable, and again states that broad statements of utility, as in the cited claims cannot be deemed in compliance with 35 USC §101 and 35 USC §112, 1st paragraph. He also repeats that all cardiovascular diseases cannot be considered one use of the applicants' compounds. These points have all been discussed in the applicants' response above.

Patent Office personnel are informed that because a strike-through associated with punctuation marks such as a comma, semicolon, colon, or period is difficult to see, in making amendments to certain of the claims, some language is deleted and re-inserted in order to clarify the amendments with respect to affected punctuation marks. Any such deletion/re-insertion does not affect the meaning or scope of the claim in which it occurs. Similarly, because a strike-through of a single letter or a few letters of a word is difficult to see, when a word is to be modified, the entire word is deleted and the modified form of the word is re-introduced.

In view of the above amendments and arguments, it is believed that the examiner's concerns expressed in the official action of 12/24/2002 have been fully addressed. Reconsideration and further prosecution of this application are accordingly requested.

Respectfully submitted,



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